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U.S. Environmental Protection Agency
SCIENCE ADVISORY BOARD
Residual Risk Subcommittee
Research Triangle Park, NC
March 1-2, 2000

PRESENT:

Dr. Philip Hopke, Chair
Dr. Gregory Biddinger
Dr. Stephen Brown
Dr. Deborah Cory-Slechta
Dr. Thomas Gentile
Dr. Dale Hattis
Dr. Michael McFarland
Dr. Paulette Middleton (by phone on 3/1 from 1:30-2:30 for discussion of Q 3&4)
Dr. Jerome Nriagu
Dr. George Taylor
Dr. Valerie Thomas
Dr. Rae Zimmerman

Designated Federal Officer: Dr. Donald G. Barnes

Other attendees in the room are noted on the Sign-in sheets. (Attachment A). Others who identified themselves on the phone were the following:

Dr. Ben Parkhearst, Cadmus, Group
Mr. William Bill Sills, Michigan Department of Environmental Quality (DEQ)

The Federal Register notice (Attachment B) and the agenda (Attachment C) for the meeting are attached.

I. Opening

In the absence of Dr. Hopke, who was delayed in travel, Dr. Brown opened the meeting with a brief description of SAB's involvement with the Residual Risk issue in the past. He then initiated the Public Disclosure process. Based an examination of the Confidential Financial Statements (Office of Government Ethics Form 450), it had been determined by the SAB Staff that none of the Panelists had a legal conflict-of-interest. The Public Disclosure process is a voluntary mechanism for sharing backgrounds of each participating Panelist that might be of interest to other Panelists and the public.

Among the items shared were the following:

Dr. Brown had been a member of the Executive Committee that reviewed the report of Residual Risk 1 Panel. He had experience with ENSR using methods very similar to those used in this document.

Dr. Gentile had been a member of the Residual Risk 1 Panel. There is a secondary lead smelter in NY, but it had been regulated before he joined.

Dr. Zimmerman had been a member of the Residual Risk 1 Panel. She has had funding from EPA, primarily through Superfund. Her memberships include ORD's Board of Scientific Counselors (BOSC) and National Research Council (NRC) panels. She has not worked directly on Pb smelters.

Dr. Cory-Slechta has conducted research on lead. She has not received funding from people associated with the lead industry.

Dr. Hattis has not received funding from lead interests. Some years ago he developed a pharmacokinetic model for lead for the Occupational Safety and Health Administration (OSHA).

Dr. Thomas identifies herself as having pro-environment views. Her leaning is towards maximal use of data and model simplicity. She has published articles on Pb and Pb industrial ecology. She published a recent article on Pb in former USSR, showing that recycling of Pb batteries needs be conducted with careful supervision. She is associated with an international group trying to minimize adverse environmental impacts of lead. She has received no funding from the lead industry. Her funding sources include AT&T, MacArthur Foundation, and W. Walton Jones Foundation.

Dr. McFarland is a member of the SAB's Environmental Engineering Committee.

Dr. Taylor had been a member of the Residual Risk 1 Panel . He has been a Consultant to the SAB's Clean Air Scientific Advisory Committee (CASAC).

Dr. Biddinger had been a member of the Residual Risk 1 Panel. He has worked at Cornell, with the Illinois Dept of Env Conservation, and managed an Exxon plant in California.

Dr. Nriagu is a member of the SAB's Integrated Human Exposure Committee (IHEC). He has not done anything directly on Pb smelters. He has had grants from EPA. He has served on an NRC panel on Pb. He serves on a group interested in childhood lead in Washington, DC. He has worked on a number of lead issues that have brought him attention in the popular press; e.g., recent public reports on Pb in candles. He has not received funding from the lead industry.

Dr. Brown asked the members of the public to introduce themselves.

II. Agency presentations

A. Introduction

Mr. Dave Guinnup reminded the group that they were being asked to review the residual risk method, not the final product for the case of Pb. The current effort should b e viewed as a work in progress.

Ms. Kelly Rimer provided an introduction to the topic (Attachment D). The Agency needs to make a decision on this source category by 2003; therefore, this effort is still very much a work-in-progress. The document that the SAB has been asked to review is not a decision document. For example, the eco analysis has only been conducted at a screening level. More detailed analytic methods are not yet available to apply to the eco aspect of the case. Also, in the health arena, only individual risks have been generated, to date; the final document will have population risks also.

Qs&As/Discussion session: Points made included the following:

1) The Agency has not talked with the National Institute of Environmental Health Sciences (NIEHS) in depth about this issue.
2) The Agency has been working on the screening approach for two years and on the uncertainty and variability portion since only last fall.
3) Many of the same methods are being used by OSW. [There was some SAB concern about any impact that this review might have on those OSW decisions.]
4) "Ample margin of safety" has been interpreted to mean that a 1-in-a-million risk for most exposed individual will trigger further analysis. Historically, The Agency expects that the final decision, based upon the more extensive analysis, might result a final acceptable risk of 1-in-10,000.

B. Screening Risk Assessment

Ms. Kelly Rimer provided a discussion of the topic (Attachment E).

Qs&As/Discussion session: Points made included the following:

1) What is the impact of not considering complex terrain and building downwash? Ans: This is not a problem since most of the terrain around the plants is not complex, and the downwash is not likely to be a problem. Besides, fugitive emissions were the driver, and the point of concern was off-site. The Agency might explore the impact of complex terrain and downwash.
2) What is the impact of assuming that all Chromium is Cr(VI)? Ans: Didn't look at it.
2) Conservatism. Agency wants to be conservative, but not too conservative. They need to be consistent between plants/sources.
3) The extent to which the fugitive emissions are captured often has a big impact. This was also true in New York, but not everywhere.

[Dr. Hopke joined meeting, took the position of Chair (expressing his thanks to Dr. Brown), and gave his disclosure.]

C. Multipathway Analysis

Dr. Nancy Jones (EPA contractor) provided a discussion of the topic (Attachment F). Among the points she made were that risks to the hypothetical home gardener were greater than the risks to the hypothetical farmer, primarily because the farm was assumed to be farther away from the

plant. Metals drove the assessment to a greater extent than did than organics. The major pathway of concern was via deposition onto produce that was eaten unwashed. Some Subcommittee Members questioned whether this scenario was realistic in the real world.

Qs&As /Discussion session: Points made included the following:

1) The Agency will get better data/info from the industry in future iterations.
2) The Agency's Exposure Factors Handbook was used for many data.
3) There were questions about the IEM-2M model, particularly how it dealt with mercury. The model was modified (e.g., Hg-specific equations, were removed for non-mercury HAPs), but the nature and extent of further modifications were not clear to the Members.
4) There was concern about the treatment of background levels of the contaminants.
5) Emissions were speciated by HAP to lead ratios at the 4 plants in the more refined assessment. Speciation will be more fully considered in future iterations depending upon newly acquired data. Future iterations will allow for more fully considering other aspects of the IEM-2M model.
6) The Agency is developing newer models, (e.g., TRIM) but they might not be ready in time for use with this source category.
7) Mr. Gentile described more data that he felt would be available from the states (and possibly from the industry) that could be of value to this exercise. He noted the Agency's use of a mixture of conservative (high-end) and best-estimate (mid-range) assumptions.
8) The Agency is not treating the non-cancer effects of chlorinated dibenzo-p-dioxins and dibenzofurans (CDDs/CDFs), because the Agency does not currently have approved dose-response (D-R) information for these effects. If they don't have D-R data, then they effectively ignore the effect. It was not clear to all Members that non-cancer effects of CDDs/Fs should be ignored here, since it appeared that they are not ignored by other Agency programs. EPA noted that for CDDs/CDFs there is now a new dose-response assessment whcih will be used in the final iteration of the analysis ( it was unavailable at the time EPA conducted the initial analysis).
9) Start-up and upset conditions at the plant were not considered in the screening analysis, but they are included in the uncertainty and variability assessment that is a part of the more refined analysis.

BREAK

At the request of the Panel, Mr. Kevin Cavender gave a short presentation on the current MACT standard and the devices/techniques that are used to met them. Principally, these involved the use of some afterburners, some hoods, and some housekeeping. Stack emissions were pretty well-controlled already, although the installation of afterburners made a big impact in some cases. The controls are of the end-of-pipe variety, given the Act. There are some experimental innovations

(elctrowinning), but these can't be required in this exercise. Baghouse waste goes back into the process.

D. Uncertainty and Variability Assessment

Mr. Robert Hetes provided a discussion of the topic. (Attachment G)

Qs&As/Discussion session:

A series of issues were discussed.

III. Public Comment

A. Dr. Elizabeth Anderson, Sciences International, on behalf of the Residual Risk Coalition.

Dr. Anderson's written comments had been distributed to the Subcommittee by the DFO before the meeting (Attachment H). She distributed copies of her overheads (Attachment I).

B. Dr. Teresa Bowers (Gradient Corporation) on behalf of Association of Battery Recyclers and the Lead Industries Association

Dr. Bowers's written comments had been distributed to the Subcommittee by the DFO before the meeting (Attachment H). She distributed copies of her overheads (Attachment I).

A Subcommittee Member asked why industry was not forthcoming in providing better data. In response, an industry representative in the audience, Mr. Russ Kemp, stated that there are good data available for ground-truthing, principally from the states, that include both monitoring data and emissions data. Extrapolating from one facility to another is a problem. Pre- and post-MACT stack emissions data are about the same. Fugitive emissions are the big problem. A Member noted that there are two published studies from around these plants. The "grey literature", principally from public health departments, would likely contain information from around other plants.

A Member noted that battery technology was changing and that that might have an impact on future emissions

C. Other submissions from the public

The following additional written submissions from the public were available at the meeting:

1) Mr. Billy Nichols of IDEA ??? Corp. on behalf of Sanders….(Attachment L)
2) Mr. ??? from the Indiana Department of ???(Attachment M)
3) Dr. Edmond Crouch and ??? ??? from the School of Public Health and Harvard Univ. (Attachment N)

IV. Discussion of the Charge Questions

A. Charge Question 2: Model Inputs

Dr. McFarland (Lead Discussant) provided written comments (Attachment O) that were distributed at the meeting.

Dr. Middleton (Associate Discussant) joined the meeting by phone. Her written comments had been distributed to the Subcommittee and were available at the meeting (Attachment P).

Other comments made during the discussion included the following:

1) Some Members felt that the information was not described clearly enough. It wasn't clear that the limited testing would have provided a confident view of the conditions. To get a better sense of fugitive emissions one could use more monitoring devices, make inferences from other industries, and/or make more comparisons between modeling and monitoring data.

2) Some Members questioned the method's ability to address area sources (e.g., waste ponds), biologics (e.g., viruses), and aerosols. The Agency responded that aerosols are addressed in the current analysis.

The Agency passed out Monitored Air Concentration: ISC model results (Appendix C) (Attachment Q).

B. Charge Question 3: Models

Dr. Nriagu (Lead Discussant ) found the models to be acceptable and appropriately applied, but he and others questioned whether there might be a need for a more sophisticated model for this case. A number of problems were identified with the IEM-2M model. In particular, it was not clear what modifications were made to the model. Also, one should not forget that models are like an abstract painting: many people find them to be pretty, but some people tend to read too much into them.

Dr. Middleton (Associate Discussant) had submitted her comments in writing that had been distributed and were available at the meeting (Attachment P). She agreed that there were problems with IEM-2M model. She did not have a good feeling that the values helped the bottom line. More discussion in the document might alleviate that concern.

Dr. Gentile presented data from Pb smelter in NY.

Other comments made during the discussion included the following:

1) Dr. Thomas frankly did not believe the results. In her view, the problem is inherently complex, even unworkable. She is concerned that the Agency will push forward anyway. The Agency people here at the meeting are principally model users, not model developers and have to get their job done somehow. What is the long-term trajectory of regulations and models? The Agency needs to protect itself from people (like some of her colleagues in academia) who will with dismiss the model results on its face. The Agency should try to figure out other ways of flagging where the risks might be high; e.g., compare modeling results to other emitters where there are known problems, compare these results with those regulated in other industries, etc. At a minimum, the Agency should open up the process so that people can understand what is

actually being done within the model. The results of each step in the analysis should be presented, rather than just an overall bottomline. Currently, the model is presented as a black box, the results of which cannot be reproduced easily, even by an informed reader

2) Others agreed that the lack of clarity was a problem. The models themselves are probably OK, but it is difficult to find the right parameters. The Agency should use of the model in several cases and learn through experience. However, near-term dependency on the results for making a decision is a problem; cf., some of the unrealistic values obtained for lead in this case. Therefore, the Agency needs to be clear about what the model is being asked to do and how its results will be used. Until better models and their validation appear, this may be the best that can be done. The answer to the question "Is it good enough?" depends on that question being asked.

C. Charge Question 4: Choice of Receptors

Dr. Thomas (Lead Discussant) felt that there was a series of questions that should be asked, including the following:

a. Are these the right receptors for a policy decision? Yes, from a policy point of view.

b. Are we missing somebody? Yes, workers and families. The document should acknowledge that. Other population possibilities are some folks who drink lots of milk and women of child-bearing age).

c. Are we depicting the real world? In real world, there are background levels of these contaminants. They should be considered here, as well.

Dr. Hattis (Associate Discussant) provided written comments (Attachment R) that were distributed at the meeting. He is not convinced that these are the highest levels. He was relieved to hear that hand-to-mouth exposure had been considered. He is concerned that, as yet, there is no population level analysis of risk. The current, sole focus on high-end exposed individuals is troublesome, especially when viewed in light of the possible consequences of a decision.

Mr. Mike Duestzina described how the population risk would be developed.

Other comments made during the discussion addressed the following:

a. Concern about the centroid method.

b. Extreme assumptions are counterproductive and lack credibility.

c. Perhaps the SAB needs to give the Agency permission to approximate.

II. Agency presentation (cont'd)

E. Eco-screening Risk Assessment

Dr. James White provided a discussion of the topic (Attachment S). Dr. Ben Parkhurst of Cadmus (contractor) joined by phone to answer questions, as needed. Dr. White noted that the

Agency had used the Eco RA GLs approach, including Problem Formulation. In addition, the Agency used human health-based TEQs for CDDs/CDFs for the ecological considerations.

Qs&As/Discussion session: Points made included the following:

1) The assessment is driven by fugitive emissions.

2) The Agency assumed that 1% of the chromium is Cr(VI).

3) In response to a question, the Agency reported that the eco assessment starts with the multipathway exposure, since that analysis had already been done by the time eco considerations were examined. There was some Subcommittee concern expressed that an ecologically important pollutant could have escaped at the screening level. Apparently, in the future, there will be eco-screening analysis, as well as a health-screening analysis.

4) There was concern expressed at the absence of consideration of top carnivores in the analysis.

5) Some Members also questioned whether the simply summing of HQs (metals, organics, different endpoints, etc.) to get to an HI might be setting an unfortunate precedent, even if everyone agrees today that it is not appropriate scientifically.

6) The Agency agreed that consideration of livestock could be useful.

IV. Discussion of the Charge (contd)

D. Charge Question 5: Ecological Risk Assessment

Dr. Taylor (Lead Discussant) provided written comments (Attachment T) that were distributed at the meeting. He urged a risk assessment (RA) approach, as opposed to what he called a risk characterization (RC) approach used by the Agency in this case. The first Residual Risk report (RR1) was all very general. The current document has somewhat more substance; but, again, it looks as if ecological concerns have been left to the last. In fact, there will quite likely be places in the West where eco risks will drive the overall risk. The analysis is quite limited; for example, it says nothing about the structure and function of ecosystem or about the endangered species issue. He would like some assurance that an ecological RA is, in fact, coming. He feels that the eco RC analysis may indicate a problem but that the eco RA would show that a true risk does not exist. The Agency answered that for future source categories, there would, indeed, be ecological RAs, due to resource and time constraints, there would not be one for lead smelters..

. Among his other points were the following:

1) The model is probably OK. However, there should be some way to handle area sources, e.g., waste ponds, etc.

2) The model is not clear about the extent of the region considered.

3) The model appears to have been applied correctly.

4) It is not clear how deposition velocity was handled.

5) It is not clear whether the background concentration will be in or out.

Dr. Biddinger (Associate Discussant) provided written comments (Attachment U) that were distributed at the meeting. He found the lack of a risk management context (RM) to be disconcerting. He, too, felt that the document was far short of an ecological RA of the type described in the Agency's Eco RA GLs. He quoted the act: "Adverse" means "widespread, significant adverse environmental effect". These terms need to be defined and treated in this context. The Agency needs to be clear about a) what it is doing and how and b) what the document is meant to be and what it is not meant to be. He expressed concern about summing too much into the HI, by including additional endpoints and different mechanisms of action. He thought it would be helpful if the Agency were to draw the technical community together to define these terms and reference values.

E. Charge Question 6: Health Risk Assessment

Dr. Cory-Slechta (Lead Discussant) provided written comments (Attachment V) that were distributed at the meeting. She found the presentation of data to be OK. She expressed concern about the rationale given for the hierarchy of toxicity data. She felt better about the explanation provided by Deirdre Murphy at the meeting and urged that it be more prominently featured in the document.

In her view, the HIs don't seem to lead anywhere. The additivity assumption of toxicity implicit in the HI is, of course, problematic.

She felt that the Agency was not current with trends in toxicology that are questioning the threshold concept for non-cancer endpoints.

Dr. Zimmerman (Associate Discussant) provided comments at the meeting that were distributed (Attachment W ).

Other comments made during the discussion included the following:

1) HI is a safety assessment quantity, not a risk assessment quantity.

2) The Agency should look at differences in severity of various endpoints.

3) Releases to the air are not expected to result in ground water problems. Therefore, the model does not consider that possibility.

4) There was concern about the apparent lack of consideration of chemicals for which there were no "Agency confirmed" toxicity values; e.g, the non-cancer effects of CDDs/CDFs. Some Members felt that the Agency has old values and ATSDR has new ones that could be used, rather than just ignore it all together..

5) The old NOAEL/UF approach should be replaced as we learn more about compounds; e.g., lead.

F. Charge Question 7: Uncertainty and variability (U&V) assessment

Dr. Brown (Lead Discussant) provided written comments (Attachment X) that were distributed at the meeting. He felt that the U&V assessment had been added on at the end of the exercise. The document does not clearly distinguish between variability and uncertainty. The U&V analysis should stem from the RM decision that needs to be made and the document should clearly discuss the connection. Some important areas of the document were not subjected to U&V analysis; e.g., the dose-response portion of the risk assessment, which is hard to understand. Also, it was not clear how some of the distributions were defined; e.g., emissions estimates.

Dr. Hattis (Associate Discussant) provided written comments (Attachment R) that were distributed at the meeting. He noted that there was evidence of some creative analysis here, but that it was overshadowed by several limitations. Fundamentally, there should be separate analyses for uncertainty and for variability. The approach to these analyses needs to be considered very early in the document development process so that the right information can be gathered. In addition, the U&V assessment must be sufficiently explicit that an knowledgeable reader can follow it and reproduce it. That is not the case with the current document

Other comments made during the discussion included the following:

1) The Agency indicated that they would be revisiting the U&V assessment in the final document.

2) Some Members urged the Agency to compare the predictions with the observations as a way of improving the methodology, rather than exclusively focusing on the details of the fate and transport portion of analysis.

3) The document is lacking in not having any U&V assessment for ecological issues.

G. Charge Question 8: Results Presentation

Dr. Zimmerman (Lead Discussant) summarized her written comments (Attachment W ). Associate Discussants (Dr. Cory-Slechta and Mr. Gentile) presented their thoughts (Attachments V and X.)

Other comments made during the discussion included the following:

1) The graphs that were presented as a part of the Agency's briefing at the meeting were an improvement over what was in the document and should be included in future versions; e.g., identification of the

maximumly exposed individual (MEI) and the central tendency value on the graphs.

2) There should be more discussion of the values that stand out as being particularly important, particularly suspect, and/or particularly unexpected that they call elements of the analysis into question.

3) There are likely to be more data available on blood lead levels in the "grey literature on the state and local level that the Agency would find useful.

V. Writing Assignments

The Lead and Associate Discussants were assigned the task of writing (re-writing) their response to the Charge Questions in light of the discussion/presentations at the meeting.

NEXT DAY -- Wednesday, March 2, 2000

The Subcommittee gathered in the EPA Auditorium by 8:00 AM and worked in small groups compiling their comments into a single response for each of the Charge Questions. This information was printed, copied, and distributed to the entire Subcommittee, Agency personnel, and members of the public (Attachments ). [The Subcommittee expressed appreciation for the access to computer facilities that the Agency had provided. These arrangements helped the work of the Subcommittee to proceed much more quickly]

At 10:30, the Chair reconvened the group in plenary session and granted Ms. Rimer and the Agency team permission to address the Subcommittee in public session in order elaborate upon/respond to some of the comments made the previous day:

1) Mr. Hetes acknowledged that the U&V analysis was incomplete and was addressed after much of the work on the project had been completed. The Agency agrees that the risk management issue as posed by the Subcommittee ("A risk of X is experienced by Y percentile of the population with Z level of confidence") is of primary importance and that uncertainty and variability analyses would ideally be assessed separately. However, such a task is difficult to do, and it would be unfortunate to give the results an appearance of precision that they do not merit. In the view of the Agency's consultant on this matter, Dr. Christopher Frey, the data are not good enough to conduct an ideal U&V assessment in this case. Therefore, guidance from the SAB would be most helpful.

2) Again, this document is not a an endproduct in a regulation supporting exercise. The Agency realizes that the focus should be on population risk, not individual risk, and make it so in the final analysis.

3) Model validation is a big issue in this case and in all cases of computer models. The Agency is considering field study evaluation of the models; however, everyone understands that this is not going to happen quickly or easily. In the meantime, the Agency is under a legislative mandate to reach decisions soon. Again,

guidance from the SAB would be most helpful. This guidance is especially needed for source categories other than lead smelters, where the data will be even more scarce.

Qs&As/Discussion session: Points made included the following:

1) Find data if you can. Reality checks are needed.
2) As one way of reducing analytic resource requirements, one could assume a distribution of variability and run a Monte-Carlo analysis on the uncertainty.
3) There is great value in looking at the data from both -- separately -- the variability and the uncertainty points of view.
4) Such analyses are indeed resource intensive, but it is better to address the issue before the fact than to have it all thrashed out in a litigation forum. (Reference was made to comments submitted by Dr. Crouch (Attachment Y) that identified a series of shortcomings in the method.)
5) The Agency should do the first residual risk analysis as well as it can, since it will be a prototype of future analysis. In this context, resources expended on the analysis should be considered to be a capital investment.
6) Whatever the Agency does, it should be clear about what it does. Such an approach would include an open discussion of models, and the fact that some of them may never be able to be "validated" in a strict sense of the term.

[Michigan Dept of Environmental Conservation joined the call.]

7) The Agency needs to realize that gaining high confidence for outliers in a distribution can be expensive and time-consuming. Such outliers can be important if they have a significant impact on the decision. Therefore, one should keep in mind that there is no more expensive analysis than one that gets to the wrong answer.

IV. Discussion of the Charge (contd)

H. Charge Question 5: Overall

Dr. Hopke (Discussant) summarized his draft (Attachment Z). He called attention to the last paragraph that described the Agency approach as "generally reasonable". This description engendered considerable discussion, which included the following points, which are not presented as consensus statements:

1) What does the Subcommittee recommend that the Agency do next? Obvious options include a) "polishing" the model -- which would leave many of the fundamental problems untouched and b) gathering much more data -- which has obvious resource constraints. An alternative would be to conduct some more industry sectors analyses and adjusting (improving) the model to deal with the problems that would be revealed in these exercises. This latter approach would not likely result in a method that would generate quality, near-term

decisions, but, in the longer run, it should lead to better information for better decisions.

2) Science does not generate precise estimates of risks; rather, it indicates areas where potential problems may exist. The current exercise does not calculate risks; rather, it presents modeling results. The approach needs to gain credibility through application to many other sectors.

3) The Subcommittee's discussion has focused on how to do the analysis better, but with relatively little on how to do the analysis differently. In short, if the Agency does not do the analysis this way, what is the alternative?

4) At least it can be said, although it is not a strong endorsement, that the proposed approach is consistent with current practice.

5) The ecological analysis is weak. The Agency has not delivered on what some of the Members felt had been promised in the Report to Congress. They see little reason to draw comfort from additional protestations that things will be done differently in the future. The fear is that the Agency will go no further than the inadequate job in this document. There needs to be a much more explicit discussion of what will be done in the next iteration.

6) The IEM-2M model is not science-driven. It depends on many different default values, some of which may not be routinely application. For example, a structure-activity default strategy may be effective for some organics, but it has not been shown to be effective with metals.

7) These comments seem to indicate that, overall, what the Agency has done is reasonable, in light of the constraints.

8) The Agency should identify those parts of the model that are driving the risk and examine the associated computer code in detail.

9) The underlying problem is to understand the best way to parameterization models in situations in which a) the models are increasingly complex and b) the data are limited in extent and compatibility.

10) The Agency asked, "Should the model results be used for decisions?" Some Subcommittee Members answered that the Agency should not oversell the results of the analysis. The model results are <u>not</u> the risks themselves; rather the results are indicative of the situation and should be used to inform the decision (perhaps by comparing the results of the application of the model to several sectors) and not to determine the decision, *per se*. Another approach would be to use a range of experts to apply their judgment in evaluate modeling results and, thereby, to generate a probabilistic estimates of the risk.

11) All of this points up the need to have an understanding of the risk management (RM) framework that will lead to the eventual decision. The reader should also be given information on the impact of proposed remedies.

LUNCH

After lunch the Subcommittee reviewed written drafts of the responses to the Charge Questions 2-8, some of which had been edited in response to comments received during the morning (Attachments AA - GG ).

The Chair summarized the major points that he will include in the transmittal letter to the Administrator; i.e.,

1)
2)
3)
4)

There being no further discussion forthcoming, the meeting was adjourned at 1:45 PM.

Respectfully submitted

Donald G. Barnes, PhD
Designated Federal Officer

Philip Hopke, PhD
Subcommittee Chair

ATTACHMENTS

Attachment A -- Sign-in sheets
Attachment B -- Federal Register Notice announcing the meeting
Attachment C --Agenda
Attachment D -- Copy of overheads used for Agency's Introduction presentation
Attachment E -- Copy of overheads used for Agency's Screening Assessment presentation
Attachment F -- Copy of overheads used for Agency's Multi-pathway presentation
Attachment G -- Copy of overheads used for Agency's Uncertainty and Variability presentation
Attachment H -- Dr. Elizabeth Anderson's (Sciences International) comments on behalf of the Residual Risk Coalition.
Attachment I -- Copy of Dr. Anderson's overheads used in her presentation
Attachment J -- Dr. Teresa Bowers's (Gradient Corporation) on behalf of Association of Battery Recyclers and the Lead Industries Association
Attachment K -- Copy of Dr. Bowers's overheads used in her presentation
Attachment L -- Comments of Mr. Billy Nichols, on behalf of Sanders.....
Attachment M -- Comments of Mr. ???? from the Indiana Department of Environmental ???
Attachment N -- Comments of Dr. Edmond Crouch and Dr. ??? ??? (???) on their own behalf.
Attachment O -- Dr. McFarland's pre-meeting comments
Attachment P -- Dr. Middleton's pre-meeting comments
Attachment Q -- Monitored Air Concentration: ISC model results. Appendix C
Attachment R -- Dr. Hattis's pre-meeting comments
Attachment S -- Copy of overheads used for Agency's Eco Risk Screening
Attachment T -- Dr. Taylor's pre-meeting comments
Attachment U -- Dr. Biddinger's pre-meeting comments
Attachment V -- Dr. Cory-Slechta's pre-meeting comments
Attachment W -- Dr. Zimmerman's pre-meeting comments
Attachment X -- Dr. Brown's pre-meeting comments
Attachment Y -- Dr. Edmond Crouch's comments
Attachment Z -- Draft response to Charge Question 1
Attachment AA -- Draft response to Charge Question 2
Attachment BB -- Draft response to Charge Question 3
Attachment CC -- Draft response to Charge Question 4
Attachment DD -- Draft response to Charge Question 5
Attachment EE-- Draft response to Charge Question 6
Attachment FF -- Draft response to Charge Question 7
Attachment GG -- Draft response to Charge Question 8